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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Marie-Laure Fardeau

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EXAMINER

KIM, TAEYOON

ART UNIT

PAPER NUMBER

1651

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/538,715	Applicant(s) FARDEAU ET AL.	
	Examiner TAEYOON KIM	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,8 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,8 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
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| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 8 and 12 are pending.

Response to Amendment

Applicant's amendment and response filed on 11/27/2007 has been received and entered into the case.

Claims 2-7 and 9-11 have been canceled, claim 12 is newly added, and claims 1, 8 and 12 are pending and have been considered on the merits. All arguments have been fully considered.

The objections to the specification have been withdrawn due to the amendment.

The claim rejection under 35 U.S.C. §112, 1st para., has been withdrawn due to the amendment.

The claim rejection under 35 U.S.C. §101 to claims 1-7 has been withdrawn due to the amendment. Claim 8 remains rejected (see below).

With regard to the claim rejection under 35 U.S.C. §112, 2nd para., based on "metes and bounds" requirement, the applicant stated that the metes and bounds of the claimed invention will be clearly distinguished by one of ordinary skill in the art. This argument is not persuasive because the limitation disclosed in claim 1 is drawn to any strain of *Exiguobacterium* genus. The current claim discloses any isolated strain which can hybridize any portion of genomic or plasmid DNA of the deposited strain. It is well known in the art that there are highly homologous region of 16S rRNA gene of *Exiguobacterium lactigenes* strain 10C shared among various *Exiguobacterium* strains as listed in the BLAST search report having high percentage of from the previous office

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action. Therefore, it is clear that many, if not all, *Exiguobacterium* strains share significant amount of homology each other in 16S rRNA sequence, and thus, same with the deposited strain (No. I-2962), rendering other *Exiguobacterium* strains being capable of hybridizing to the deposited strain. Thus, the current claim is drawn to any *Exiguobacterium* strain. Since the claim does not clearly point out the subject matter intended for the claimed invention, and it does not appear that the applicant claims any *Exiguobacterium* strain, the metes and bounds of the claim intended in the application has to be defined. Therefore, the claim rejection under 35 U.S.C. §112, 2nd para., is still valid.

The argument to the claim rejection under 35 U.S.C. §102 based on Drancourt et al. Farrow et al. Fruhling et al. in light of BLAST search report is not persuasive. Applicant argued that the rejection was based on the now-cancelled claim(s), and the amendments are believed to obviate the rejection. The claim rejection was based on the disclose of claim 1, which claims any *Exiguobacterium* strain having a property to hybridize the DNA of the deposited strain. Clearly the references teach strains having the disclosed property of the current invention.

Claim Objections

Claim 8 is objected to because of the following informalities: The term "The bacterial strain" appears to be more appropriate as "A bacterial strain". Appropriate correction is required.

Claim 12 is objected to because of the following informalities: The term "the sequence" in claim 12 is more appropriate with "a" instead of "the". Appropriate

correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 8 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The intended scope and meaning of the claimed invention are unclear. Applicant claims any bacteria strain having a DNA sequence hybridizing with the genomic or plasmid DNA of a strain deposited under No. I-2962, but does not set forth the metes and bounds of neither the specific strain intended nor the metes and bounds of the DNA sequence which hybridizes with the DNA of I-2962 in the cited claims. Critical elements of applicant's invention appear to be missing from the cited claim(s) as it would appear that the claims as written would read on ANY strain of *Exiguobacterium* genus that would not appear to be applicant's invention. It is notoriously old and well known in the art of *Exiguobacterium* genus, and they share significant portion of their genomic DNA sequences and thus can hybridize each other. It would appear that applicant's invention requires more than simply the whole genus of *Exiguobacterium* and it would not appear that applicant intended to claim said the entire *Exiguobacterium* genus.

Furthermore, it is not clear whether the DNA sequence of the bacteria strain is genomic DNA or a plasmid DNA exogenously introduced or the two bacteria strains are identical. The claim can be interpreted as drawn to any bacteria having a piece of the

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genomic or plasmid DNA of *Exiguobacterium lactigenes* under the No. I-2962 either endogenously present or exogenously introduced. It appears that the current invention is drawn to a specific bacteria strain deposited as *Exiguobacterium lactigenes* under the No. I-2962, rather than any bacteria comprising at least a piece of DNA sequence from *Exiguobacterium lactigenes* under the No. I-2962. Therefore, it is unclear what the intended scope of the cited claims is, the claims must be considered indefinite and rejection under the second paragraph of this statute is appropriate.

Claim 1 discloses the phrase “the order of” and it is not clear what the subject matter the phrase intends to point out. The term “order” is considered as the class of scale or magnitude of any amount, and 40 and 50°C is considered as the same order of 2. The expression of “the order of 40 to 50°C” is therefore vague what the phrase intends to point out whether the claim intends to point out the range of temperature being 40 to 50°C or all temperature range having the order of 2. It appears that the temperature being simply in the range of 40 to 50°C. Applicant is advised to amend the claim.

The term “said strain” in claim 1, line 7 does not clearly point out which strain the term intends to claim. There are two strains: an isolated bacterial strain, and the deposited strain. Clarification is required.

Claim 1 discloses the term “its DNA” for the content of a G+C being approximately 50 mol%. It is not clear which portion of DNA the claim intends to point out. The G+C content would vary depending on the position of the DNA and without specific positions and length of the sequence, it is not enable to measure the content.

Claim 8 recites the limitation "The bacterial strain" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "the bacteria strain". It appears that there are two bacteria strains disclosed in claim 1, and it is not clear which bacterial strain the limitation of claim 12 intends to point out. For search purpose, the bacteria strain is interpreted as any bacterial strain having similarity with *Exiguobacterium lactigenes* under the No. I-2962.

Claim 12 discloses the limitation of "characterized by the sequence..." It is not clear whether the limitation intends to claim that the bacterial strain possesses the sequence or hybridizes the sequence, etc. It appears that the bacterial strain contains the sequence. Clarification is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 8 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention does not fall within at least one of the four categories of patent eligible subject matter recited in 35 U.S.C. 101 (process, machine, manufacture, or composition of matter). The standard for patentability in the area of living organisms and biomolecules is whether the claimed matter "is the result of human intervention." See M.P.E.P. § 2105.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102 (b) as being anticipated by Drancourt et al. (2000; IDS ref.), Farrow et al. (1994; IDS ref.) or Fruhling et al. (2002; IDS ref.) in light of BLAST Basic local alignment search.

Claim 1 is drawn to an isolated bacterial strain having a DNA sequence capable of hybridizing with genomic or plasmid DNA of a strain deposited under the No. I-2926, and the isolated bacterial strain having listed properties in the claims.

Drancourt et al., Farrow et al. or Fruhling et al. in light of BLAST and NCBI search results disclose a bacterial strain designated as AF227839, X70316.1, or AJ344151, respectively, which has ability to hybridize with the sequence of AY818050. Since AY818050 is the identical sequence as 16S rRNA sequence of *Exiguobacterium lactigenes* under the No. I-2962, the bacterial strain of Drancourt et al., Farrow et al. or Fruhling et al. anticipates all the limitations disclosed in the current claims. Since AF227839 is identical as the bacterial strain as the claimed invention, the properties disclosed are considered as inherent properties of the bacterial strain of Drancourt et al., Farrow et al. or Fruhling et al.

M.P.E.P. §2112 states that “The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer.”

Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir.

1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that “just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel.”

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' bacterial strain differs, and if so to what extent, from the bacterial strain discussed in Drancourt et al., Farrow et al. or Fruhling et al. Accordingly, it has been established that the prior art bacterial strain, which meets the limitation of the claims, demonstrates a reasonable probability that it is either identical or sufficiently similar to the claimed bacterial strain that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

Merely because a characteristic of a known bacterial strain is not disclosed in a reference does not make the known bacterial strain patentable. The new bacterial strain possesses inherent characteristics which might not be displayed in the tests used the reference. Clear evidence that the bacterial strain of the cited prior art do not possess a critical characteristic that is possessed by the claimed bacterial strain, would advance

prosecution and might permit allowance of claims to applicants' bacterial strain.

Thus, the reference anticipates the claimed subject matter.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAEYOON KIM whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 4:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford Jr/

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